REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 24-28 are pending in the present application. Claims 24-28 have been amended to address the formal matters raised in the outstanding Official Action. As the changes tot eh claims only address formal matters. Applicant do not believed that any new issues are raised in the present amendment that would require a further search and consideration of the claimed invention. Accordingly, applicants request the entry of the present amendment. At they very least, applicants believe that the amendment places the application in better condition for appeal. Claims 15-23 and 29-32 have been canceled.

In the outstanding Official Action, claims 15, 18-19, 24 and 27-28 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Applicants believe the present amendment overcomes this rejection.

The claims were rejected for reciting the phrase "nucleic acid sequence". However, as noted above, claims 15-23 and 29-32 have been canceled. Claims 24-28 have been amended so that this phrase is no longer recited.

Claims 16-17 were rejected for reciting the phrase "consecutive bases". However, claims 16-17 have been canceled.

Claim 26 was rejected for being dependent on an improper claim. However, as acknowledged by the Examiner, claim 26 should have been dependent on claim 24. Indeed, applicants have amended claim 26 to reflect this.

Applicants thank the Examiner for her suggestions as how to overcome these informalties.

Claims 15-18 and 24-26 were rejected under 35 USC 101 for allegedly not being directed to statutory subject matter. Applicants believe the present amendment overcomes this rejection.

As suggested by the Examiner, the claims have been amended to recite a "nucleic acid". Accordingly, applicants respectfully request that the rejection be withdrawn.

Claims 15-19 and 24-28 were rejected under 35 USC 101 for allegedly not satisfying the utility requirement. This rejection is respectfully traversed.

However, applicants respectfully submit that specific and substantial utilities for the claimed invention are identified.

MPEP § 2107.01 provides that a "specific utility" is specific to the subject matter claimed and can "provide a well-defined and particular benefit to the public." In re Fisher, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). In this regard, MPEP § 2107.01 instructs that Office personnel should

distinguish between situations where an applicant has disclosed a specific use for the invention as opposed to situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, would not be sufficient to define a specific utility for the compound.

In view of the above, it is believed to be apparent that applicants plainly satisfy this threshold requirement by indicating that the nucleic acids are useful in diagnosing Parkinson's disease.

As to whether the claimed invention has a substantial utility, MPEP § 2107.01 provides that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. In other words, the substantial utility requirement necessitates that a claimed invention have a significant and presently available benefit to the public. See In re Fisher, 421 F.3d at 1371, 76 USPQ2d at 1230. MPEP § 2107.1 provides several examples of situations that would require or constitute the need to carry out further research to identify or reasonably confirm that a claimed invention have a significant and presently available benefit to the public:

1) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;

2) A method of treating an unspecified disease or condition;

3) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;

4) A method of making a material that itself has no specific, substantial, and credible utility; and

5) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Clearly, applicants plainly satisfy this aspect of the utility requirement by indicating that the nucleic acids are useful in diagnosing Parkinson's disease. Thus, while one skilled in the art may need to conduct additional experiments or research to perfect the invention, it can not be said that one skilled in the art would have to conduct additional research to establish the utility of the invention.

In fact, MPEP § 2107.01 expressly states that any reasonable use identified by the applicant provides a public benefit should be accepted as sufficient, at least with regard to satisfying the "substantial" utility requirement.

In view of the above, it is believed to be apparent that applicants have identified a specific and substantial utility.

Rather, it is believed that the Patent Office actually questions the credibility and operability of the claimed invention itself on the grounds that the utility of the claimed invention has been established with statistical evidence and that a consensus does not exist in the state of the art as to the role of ADH7 gene or its alleles/polymorphism in Parkinson's disease. Accordingly, the Official Action contends that further experimentation is required to establish the asserted utility of the claimed invention. In support of its position, the Official Action cites to several publications (TAN, BURNEVICH, and LUCNETINI) in support of its position.

However, applicants maintain that the publications cited by the Official Action fail to show that the present application does not meet the requirements of 35 USC 101 for the same reasons as those set forth in the amendment of September 8, 2006 and previous responses.

Furthermore, the Examiner is respectfully reminded that there is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed, and

whether the asserted utility appears to contravene established scientific principles and beliefs. In fact, an applicant is not required to provide evidence sufficient to establish that an asserted utility is a statistical certainty. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956); *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965); see *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response).

Accordingly, applicants respectfully submit that the statistical evidence set forth in the specification is sufficient to establish the utility of the claimed invention for the same reasons as those set forth in the amendment of September 8, 2006 and previous responses and note that they are not required to provide evidence sufficient to establish the asserted utility for the claimed invention beyond a reasonable doubt or with absolute statistical certainty as apparently required by the Official Action.

As noted above, applicants maintain that the TAN, BURNEVICH, and LUCNETINI fail to constitute a sufficient amount of evidence so as to cast doubt as the utility of the claimed

invention identified by the applicant. As even acknowledged by the Official Action, the cited publications of TAN, BURNEVICH, and LUCNETINI at best, show a lack a consensus in the art concerning the role of ADH7 gene or its alleles/polymorphism in Parkinson's disease. Thus, it can not be said that the role of ADH7 gene or its alleles/polymorphism in Parkinson's disease asserted by the applicant expressly contravenes established scientific principles and beliefs.

Thus, in view of the above, it can not be said that it is more likely than not that the present disclosure does not satisfy the utility requirement.

In imposing the rejection, the Official Action states that the sole basis for the utility rejection is that the claimed invention does not have a specific and substantial utility (Official Action, pg. 7, first full paragraph).

Claims 15-19, 24 and 27-28 were rejected under 35 USC 112, first paragraph, for allegedly not satisfying the enablement requirement. Applicants believe the present amendment overcomes this rejection.

The Official Action contends that the specification does not disclose how to use nucleic acids consisting of combinations of SEQ ID NOS: 1-7. However, applicants note the claims have been amended to recite an isolated ADH7 nucleic acid consisting of one of SEQ ID NOS: 1-7. This of course refers to

the nucleic acid itself. Applicants do not disclaim the potential application of using other individual nucleic acids with the claimed invention.

In view of the above, applicants respectfully request that the rejection be withdrawn.

The Examiner advised that should claims 15, 18 and 19 be found allowable, claims 24, 27 and 28 would be objected to under 37 CFR 1.75. However, as noted above, claims 15-23 and 29-32 have been canceled. Accordingly, applicants respectfully request that the objection be withdrawn.

The specification was objected to for allegedly not satisfying the requirements for patent applications containing nucleotide and/or amino acid sequence disclosures. Accordingly, applicants submit herewith a substitute Sequence Listing.

Responsive to the requirement for submission of a Sequence Listing, imposed in the outstanding Official Action, the same is provided herewith, attached to the present amendment, in paper and disc formats. Applicants hereby state that the attached paper and computer readable copies have the same content, and introduce no new matter into the present application.

In this regard, the specification and claims have been amended so that they are commensurate with the submission of the present Sequence Listing.

In view of the above, it is respectfully submitted that the above-identified application complies with the requirements

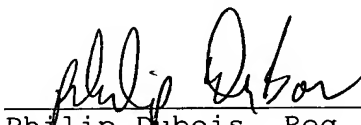
for patent applications containing nucleotide sequences and/or amino acid sequence disclosures.

In view of the present amendment and foregoing Remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Philip Dubois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/fb

Appendix

Sequence listing in paper and electronic form